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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,860	01/04/2002	Jerome B. Posner	2581.1004-004	4807

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 10/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/037,860	Applicant(s) POSNER ET AL.	
	Examiner Karen A Canella	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>April 10, 2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Acknowledgment is made of applicants election of Group I, drawn to Ma family polypeptide and fusion proteins comprising Ma family polypeptides, and the species of SEQ ID NO:7. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP ' 818.03(a)).
2. Claims 1-10 are pending. Claims 5-10, drawn to non-elected inventions, are withdrawn from consideration. Claims 1-4 are examined on the merits. Because SEQ ID NO:7 was free of the prior art, all species have been examined (SEQ ID NO: 4, 7, 9, 11 and 13)

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
Claim 1 recites "functional derivative". The metes and bounds of the term "derivative" is unclear because derivative can encompass chemical modifications of the polypeptides, or can encompass additional molecular structure without modifying the polypeptide, or can encompass both modifications and additional molecular structure. Further, the metes and bounds of the term "functional" cannot be construed. The specification states (page 6, lines 13-17) that the altered or mutant Ma family polypeptide should be an active of functional derivative of the naturally occurring polypeptide. However, no limiting definition of the functions of the naturally occurring polypeptides are set forth.
5. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 3 are drawn to an isolated Ma family polypeptide and an isolated fusion protein comprising a Ma family polypeptide, respectively.

The specification defines a "Ma family polypeptide" as a polypeptide that is expressed by brain and/or testes, and that shares a significant identity with Ma1, 2, 3, 4 or 5 (SEQ ID NO:4, 7, 9, 11, 13). The specification defines "significant identity as 75% amino acid identity with Ma1, 2, 3, 4 or 5 (SEQ ID NO:4, 7, 9, 11, 13).

It is noted that SEQ ID NO: 9, 13, 7 and 4 have 51.6%, 42.3%, 40.6%, and 38.6% sequence identity to SEQ ID NO:11, respectively. The specification describes Ma1, 2, 3, 4 or 5 (SEQ ID NO:4, 7, 9, 11, 13) as being expressed in both brain and testes (Example 2 and Example 3). The definition supplied by the specification reads on polypeptides expressed by either brain or testes rather than brain and testes. Thus, the claims are drawn to a genus of polypeptides that are highly variant, encompassing polypeptide sequence having 75% sequence identity to SEQ ID NO:4, 7, 9, 11 and 13 which differ from SEQ ID NO:11 by 51, 42, 40 and 38% sequence identity. Further, the genus encompasses proteins which differ in function from SEQ ID NO: 4, 7, 9, 11 and 13 because MA1, 2, 3, 4 and 5 (SEQ ID NO:4, 7, 9, 11 and 13) are expressed both in brain and in testes, in contrast to the definition for a Ma polypeptide which specifies expression in either the brain or the testes rather than the brain and the testes. Because the genus of encompassed polypeptides are highly variant, and the disclosure of SEQ ID NO:4, 7, 9, 11 and 13 does not adequately describe the function of the proteins encompassed by the genus, the instant claims lack adequate written description for the claimed Ma family polypeptides.

Claim 1 is drawn to functional derivatives of Ma family polypeptides. For the reasons set forth under 112, 2nd above, the metes and bound of the term "functional" and the term "derivative" cannot be defined. When given the broadest reasonable interpretation, the claim encompasses a genus of "functional derivatives" which are highly variant differing in both structure and function from the described. The description of SEQ ID NO:4, 7, 9, 11, 13 fails to describe the genus of functional derivatives because said genus encompasses polypeptides having structural and functional characteristics not represented by SEQ ID NO:4, 7, 9, 11, 13.

One of skill in the art would reasonably conclude that applicant was in possession of neither the Ma family polypeptides, nor the functional derivatives of the Ma family polypeptides.

6. Claims 1 and 3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated Ma family polypeptides comprising SEQ ID NO:4, 7, 9, 11 and 13, does not reasonably provide enablement for a genus of "Ma family polypeptides beyond those possessing said SEQ ID NO or for generic fragments of SEQ ID NO:4, 7, 9, 11 and 13. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

(A) As drawn to Ma family polypeptides beyond those of SEQ ID NO:4, 7, 9, 11 and 13

Claims 1 and 3 encompass Ma family polypeptides. The specification defines "Ma family" polypeptides as polypeptides expressed in the brain and/or testes wherein said polypeptide share 75% sequence identity with SEQ ID no:4, 7, 9, 11 or 13. It is noted that the requirements of 112 first specify that the disclosure shall be enabling for how to make and use a claimed product. While one of skill in the art can construct a polypeptide having at least 75% sequence identity to any of SEQ ID NO:4, 7, 9, 11 or 13, one of skill in the art would not know if the variant protein was over expressed in the brain or testes, required by the definition of Ma family polypeptide. Accordingly, one of skill in the art would be obliged to first isolate the Ma family polypeptide from nature before being able to make said polypeptide. Thus, conception is not achieved until the polypeptides meeting the full scope of the claims are isolated from brain and testes. Given the lack of teachings in the specification regarding the amino acid sequences of Ma family polypeptides which vary by as much as 75% from each of SEQ ID NO:4, 7, 9, 11 and 13, one of skill in the art would be subject to undue experimentation in order to make and use the broadly claimed Ma family polypeptides.

(B) As drawn to fragments of SEQ ID NO:4, 7, 9, 11 and 13

Claim 1 is drawn in part to a fragment of a Ma family polypeptide. The specification contemplates antigenic fragments and immunogenic fragments (page ?, lines ?). However, when given the broadest reasonable interpretation the term "fragment" can be smaller than

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fragments which are antigenic and/or immunogenic, and the specification has not taught how to use such small fragments.

7. Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10 a.m. to 9 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

10/4/2004


KARENA. CANELLA PH.D
PRIMARY EXAMINER